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APPLICATION NO. 08/908,395	FILING DATE 11/20/97	FIRST NAMED INVENTOR CONTHEIMER	ATTORNEY DOCKET NO. 1000001
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HM32/0624

EXAMINER SUN HOFFMAN, L

ART UNIT 1642	PAPER NUMBER
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DATE MAILED: 06/24/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/980,395

Applicant(s)
Sontheimer et al

Examiner
Lin Sun-Hoffman

Group Art Unit
1642



☒ Responsive to communication(s) filed on Mar 23, 1999

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1 and 4 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1 and 4 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. Amendment to claims 1 and 4 are acknowledged. Claims 1-4 are pending for the examination.

Rejections Maintained:

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeBin et al (Am. J. Physiol. 264/2, 33-2 (C361-C369), 1993) in view of Weiss et al (US Patent Number: 5750376, May 12, 1998).

Claim 1 is drawn to a pharmaceutical composition comprising a chlortoxin ligand which binds to glial-derived or meningioma-derived tumor cells and a pharmaceutical acceptable carrier. Claim 4 further limits claim 1 in reciting that the ligand of a chlorotoxin compound is radiolabeled.

DeBin et al teach a chlorotoxin specifically blocking chloride channels (see abstract). However, DeBin et al differ from the instant invention in failing to disclose a labeled chlorotoxin. Weiss et al teach a Western blotting assay and a radioimmune assay (see column 34, lines 16-18) which involve in labeling of an antibody, and labeling of an antibody in an immunochemistry assay (see column 36, lines 65-66).

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It would have been *prima facie* obvious for one of the ordinary skill in the art at the time the invention was made to make a composition of chlorotoxin which specifically binds to chloride channels as disclosed by DeBin and to label it. One of ordinary skill in the art would have been motivated to label a chlorotoxin or any of its fusion compound taught by DeBin et al, because it is conventional and it is taught by Weiss et al to label a ligand by a fluorescent agent or a radioisotope to target the tumor cells for the purpose of diagnosis or treatment.

Applicants argues that neither DeBin nor Weiss disclose that chlorotoxin binds to glial and meningioma derived tumor cells. However, although such binding is an uncharacterized property taught by the prior art, one of the ordinary skill in the art would have been motivated to make a pharmaceutical composition of chlorotoxin with a carrier, because it is well known for the storage purpose.

Conclusion

4. No claim is allowed.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lin Sun-Hoffman, Ph.D., whose telephone number is (703)-308-7552. The examiner can normally be reached on Monday to Friday from 7:30 am to 4:00 pm Eastern Standard Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, Ph.D., can be reached on (703) -308-4310.

Lin Sun-Hoffman, Ph.D.



April 13, 1999



PAULA K. HUTZELL
SUPERVISORY PATENT EXAMINER